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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,491	02/13/2001	Dallas L. Cloutre		8229

7590

01/31/2002

Dallas L. Cloutre  
#357  
555 BRYANT ST.  
Palo Alto, CA 94301

EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/781,491

Applicant(s)

CLOUATRE ET AL.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

**DETAILED ACTION**

***Status of Claims***

1. Claims 1-18 are pending.
2. Claims 1-18 are rejected.

***Information Disclosure Statement***

3. The information disclosure statement filed on February 13, 2001 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-18 are rejected under 35 U.S.C. 102(e(2)) as being clearly anticipated by Shrivastava et al. of U.S. Patent No. 6,221,901 B1 possessing a 102(e) date of April 22, 1999. Shrivastava et al. teach of the therapeutic administration of(-) hydroxycitrate to treat a variety of ailments including hypertension, (see column 2, lines 34-48).

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Littera et al. of EP 803,202 A2, possessing a publication date of October 29, 1997.

Littera et al. teach of the administration of hydroxycitrate, which assists in the decrease in the number of cholesterolemia and triglycerides. Accordingly, the compounds of Littera et al. are effective in treating various types of disorders, namely hypertension, (see page 2, lines 7-12 and lines 50-52).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shrivastava et al. of U.S. Patent No. 6,221,901 B1 possessing a 102(e) date of April 22, 1999. Shrivastava et al. teach of the therapeutic administration of(-) hydroxycitrate to treat a variety of ailments including hypertension, (see column 2, lines 34-48). Although the prior art reference of Shrivastava et al. teach of using the magnesium salt of hydroxycitrate it is well within the level of skill of the artisan to substitute one pharmaceutically acceptable cation for another. The determination of a dosage having the optimum therapeutic index, which includes pharmaceutically acceptable salts, is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Accordingly, the reference makes obvious the instant invention.

11. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. of U.S. Patent No. 5,626,849 possessing an issue date of May 6, 1997. Hastings et al. disclose of the administration of (-) hydroxycitric acid. In addition, Hastings et al. teach that hydroxycitric acid increases the clearance of LDL cholesterol and further that hydroxycitric acid does not cause hypertension (see abstract and column 4, lines 18-42). It is established in the art that increased levels of cholesterol can form plaques on the endothelium lining of the blood vessels, which in turn can accumulate and increase in size. These obstructions composed of cholesterol reduce the flow of blood at these plaque formations. Consequently, the pressure of the blood stream must be increased to compensate for these obstructions, which is known as hypertension. Accordingly, it the skilled artisan would have been motivated to utilize

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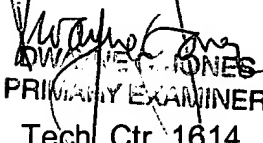
hydroxycitric acid to lower the LDL concentration in order to decrease the atherosclerotic plaques on the inner linings of the blood vessels, which would obvious lower recipients blood pressure and decrease hypertension.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

  
D. C. JONES  
PRIMARY EXAMINER  
Tech. Ctr. 1614  
January 28, 2002